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November 15, 2002

VIA COURIER

The Commissioner of Patents and Trademarks Washington, D.C. 20231 **United States of America**

Dear Sirs:

U.S. Patent Application No. 10/030,313 RE:

Applicant: Sheena M. Loosmore

MULTI-COMPONENT VACCINE TO PRTECT AGAINST

DISEASE CAUSED BY HAEMOPHILUS

INFLUENZAE....CATARRHALIS

Please find enclosed an Information Disclosure Statement and copies of the references listed therein with respect to each of the references cited in the specification, in the International Search Report received on the corresponding International application and in prior U.S. application No. 09/353,617.

Respectfully submitted,

Michael I. Stewart

Registration No. 24,973

M.I. Stewart/ac Encl.

FORM PTO-1449 U.S. DEPARTMENT OF COMMERC PATENT AND TRADEMARK OFFIC		SERIAL NO. 10/030,313
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U.S. PATENT DOCUMENTS

*INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCL.	FILING DATE
	4,496,538/					
	5,603,938 /					
	5,808,024 /					
	5,506,139 /					
	5,646,259 /	. •				

FOREIGN PATENT DOCUMENTS

	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCL.	TRANSL	ATION
	WO 96/34960 x					YES	NO
	WO 94/21290x						
	WO 94/00149						
	WO 00/35477 X						
	WO 95/34308 >						
OTHER DOCUME			Pertinent Pages, Etc.) yon-White, C. Coles, [D.W.M. Ci	rook, and	E.R. Mox	on. 1995.
	The imp	act of conjugat is. 171: 93-98.	e vaccine on carriage	of Haem	ophilus infl	uenzae ty	pe b. J.
	2./ Berkowit	z et al. 1987. J.	Pediatr. 110 :509.	-			
	3./ Claesso	n et al. 1989. J.	Pediatr. 114: 97.		1 17 1		
	4. Black, S.B., H.R. Shinefield, B. Fireman, R. Hiatt, M. Polen, E. Vittinghoff, The Northern California Kaiser Permanent Vaccine Study Center Pediatrics Group. Efficacy in infancy of oligosaccharide conjugate Haemophilus influenzae type b (HbOC) vaccine in a United States population of 61,080 children. 1991. Pediatr. Infect. Dis. J. 10:97-104.					o. b atr.	
	!		on, V.F. Burry, and L.C. e. Pediatr. Infect. Dis. J	44.457 4	100		
	6. Swaggon 1995. The pathoge	er-Fountain, L./ ne emergence ons. Clin. Infect.	e. Pediatr. Infect. Dis. J A., J.O. Hendley, E.J. C f Haemophilus influenz Dis. 21 :1322-1324.	ody, V.A. ae types e	Perriello, a e and f as s	ind L.G. D significant	onowitz.
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		APPLICANT Sheena M. Loosmore et al	
		FILING DATE July 11, 2000	GROUP N/A

	7./	uding Author, Title, Date, Pertinent Pages, Etc.) Madore, D.V. 1996. Impact of immunization on Haemophilus influenzae type b
	'."	disease. Infectious Agents and Disease 5:8-20.
	8.	Bluestone, C.D. 1982. Current concepts in otolaryngology.
		Otitis media in children: to treat or not to treat? N. Engl. J. Med. 306:1399-1404.
	9/	Ioannidis, J.P.A., M. Worthington, J.K. Griffiths, and D.R. Snydman. 1995 Spectrum and significance of bacteremia due to <i>Moraxella catarrhalis</i> . Clin. Infect. Dis. 21:390-397.
	10./	Meyer, G.A., T.R. Shope, N.J. Waeker, Jr., and F.H. Lanningham. 1995 <i>Moraxella</i> (<i>Branhamella</i>) catarrhalis bacteremia in children. Clin. Pediatr. 34:146-150.
	11	
	12,-	Barenkamp, S.J., and F.F. Bodor. 1990. Development of serum bactericida activity following non-typable <i>Haemophilus influenzae</i> acute otitis media. Pediatr. Infect. Dis. 9:333-339.
	13./	Barenkamp, S.J., and J.W. St. Geme III. 1994. Genes encoding high-molecular weight adhesion proteins of non-typeable <i>Haemophilus influenzae</i> are part of gene clusters. Infect. Immun. 62:3320-3328.
	14	St. Geme III J.W., V.V. Kumar, D. Cutter, and S.J. Barenkamp. 1998. Prevalence and distribution of the <i>hmw</i> and <i>hia</i> genes and the HMW and Hia adhesins among genetically diverse strains of non-typeable <i>Haemophilus influenzae</i> . Infect. Immun. 66:364-368
	15.,	St. Geme III, J.W., S. Falkow, and S.J. Barenkamp. 1993. High-molecular-weight proteins of non-typeable <i>Haemophilus influenzae</i> mediate attachment to human epithelial cells. Proc. Natl. Acad. Sci. USA 90 :2875-2879.
	16.*⁄	Barenkamp, S.J. 1996. Immunization with high-molecular-weight adhesion proteins or non-typeable <i>Haemophilus influenzae</i> modifies experimental otitis media in chinchillas. Infect. Immun. 64:1246-1251.
	17	Yang, Y.P., S.M. Loosmore, B. Underdown, and M.H. Klein. 1998. Nasopharyngeal colonization with non-typeable <i>H. influenzae</i> , in chinchillas. Infect. Immun. 66:1973-1980.
	18. ~	St. Geme, J.W. and D. Cutter. 1995. Evidence that surface fibrils expressed by Haemophilus influenzae type b promote attachment to human epithelial cells. Molec Microbiol. 15:77-85.
	19. 🗸	Barenkamp, S.J. and J.W. St. Geme. 1996. Identification of a second family of high molecular-weight adhesion proteins expressed by non-typeable <i>Haemophilus influenzae</i> . Molec. Microbiol. 19:1215-1223.
	20. /	St. Geme, J.W., D. Cutter and S.J. Barenkamp. 1996. Characterization of the genetic locus encoding Haemophilus influenzae type be surface fibril. J. Bact. 178:6281-6287
EXAMINER:		DATE CONSIDERED:

^{*}EXAMINER: Initial if r ference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if in conformance and not considered. Include copy of this form with next communication with applicant.

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			APPLICANT Sheena M. Loosmore et al	
			FILING DATE July 11, 2000	GROUP N/A

	21./	
		Bacterial heat shock proteins directly induce cytokine MRNA and interleukin-1 secretion in macrophage cultures. Infect. Immun. 62:5689-5693.
	22.	Loosmore, S.M., Y-P. Yang, R. Oomen, J.M. Shortreed, D.C. Coleman, and M.H. Klein. 1998. The <i>Haemophilus influenzae</i> HtrA protein is a protective antigen. Infect. Immun. 66:899-906.
	23./	Holmes, D.S. and Quigley, M. 1981. A rapid boiling method for the preparation of bacterial plasmids. Anal. Biochem. 114:193-197.
	24. /	Tabor S. and Richardson C.C., 1985. A. bacteriophage T7 RNA polymerase/promoter system for controlled exclusive expression of specific genes. Proc. Natl. Acad. Sci. 82(4): 1074-1078.
EXAMINER:		DATE CONSIDERED:

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if in conformance and not considered. Include copy of this form with next communication with applicant.